UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

SILIMED INDUSTRIA DE IMPLANTES LTDA., Plaintiff, vs. SIENTRA, INC., Defendant.	Civil Action No. 16-cv-8624 **COMPLAINT AND JURY DEMAND**

Plaintiff Silimed Industria de Implantes Ltda. ("Silimed" or "Silimed Brazil"), by its attorney Sidley Austin LLP, as and for its Complaint against defendant Sientra, Inc. ("Sientra") states as follows:

NATURE OF THE ACTION

1. This is an action for breach of contract, unfair competition, unjust enrichment, and misappropriation of trade secrets against Sientra, the North American distributor of certain breast implant products developed and manufactured by Silimed in Brazil, based on Sientra's theft, misuse, and improper disclosure of Silimed's confidential, proprietary, and trade secret manufacturing information.

2. In 2007, Silimed granted Sientra the exclusive right to distribute Silimed's breast implant products in the United States and Canada, under an April 2007 Amended and Restated Exclusivity Agreement (the "2007 Agreement"). In return, Sientra undertook to obtain and maintain necessary regulatory approvals for the distribution and sale of Silimed's products in the U.S. and Canadian markets, and in particular a pre-market approval ("PMA") from the U.S. Food and Drug Administration ("FDA"). In order to permit Sientra to meet its obligations, Silimed provided Sientra with confidential business information, including proprietary

manufacturing information related to the design, implementation, performance, and manufacturing method of its breast implant products, that was required by the FDA. The parties agreed in the 2007 Agreement that by providing such information, Silimed was not conveying to Sientra "any right or title to any [Silimed confidential information or intellectual property] by implication, estoppel or otherwise" (Section 4.4), and that Sientra was permitted to use this Silimed confidential information and intellectual property solely for the purpose of performing its obligations under the 2007 Agreement.

3. Notwithstanding these limitations, with the 2007 Agreement set to expire in April 2017, and following several failed attempts by Sientra to purchase Silimed's manufacturing operations, Sientra embarked on a secret and deliberate scheme to misappropriate Silimed confidential and proprietary information and to use that information to establish a competing manufacturing facility to replicate the Silimed line of products.

4. On August 9, 2016, Sientra publicly announced that it had entered into a services agreement with Vesta Intermediate Funding, Inc. ("Vesta"), a contract manufacturer of silicone products and other medical devices, to "establish manufacturing capacity for Sientra" and "finalize a long-term supply arrangement for its PMA-approved breast implants." The referenced PMA-approved breast implants are those developed and manufactured by Silimed, using Silimed's confidential and proprietary manufacturing information. Sientra further disclosed on August 9, 2016, that its alliance with Vesta was not newly-formed, but had been in development for "well over a year," *i.e.*, since at least August 2015. At the same time, Sientra announced that it was engaged in discussions with another potential partner.

5. In light of this disclosure, it is now apparent that Sientra has used its access to Silimed's confidential and proprietary manufacturing information – including site visits, audits,

and continuing requests for information that were represented as necessary to obtain and maintain FDA approval to distribute Silimed products – to unlawfully develop a competing manufacturing facility. When confronted by Silimed with its wrongful conduct, Sientra first sought a license which, following months of negotiation, was not provided. In the meantime, Sientra has refused to stop this wrongful behavior, even after Silimed sent multiple letters to Sientra demanding that it provide certain assurances and cease the misuse of Silimed's confidential and proprietary manufacturing information.

6. By this action, Silimed seeks a declaration that Sientra is in material breach of the 2007 Agreement, a preliminary and permanent injunction prohibiting Sientra's wrongful use and disclosure of Silimed's confidential and proprietary information, the return and/or destruction of all such information, the recovery of money damages in an amount to be determined at trial, and such further relief as this Court determines is just and proper.

PARTIES

7. Plaintiff Silimed is a corporation organized and existing under the laws of Brazil, with its principal place of business located at Rua Figueiredo Rocha, 374, Vigário Geral, in Rio de Janeiro, Brazil.

8. On information and belief, defendant Sientra is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business located in Santa Barbara, California.

JURISDICTION AND VENUE

9. This Court has jurisdiction pursuant to 28 U.S.C. § 1332 on the grounds that the parties are citizens of Brazil and Delaware, and the amount in dispute exceeds $75,000. In addition, the 2007 Agreement at issue in this case provides that New York law shall apply

(Section 10.1(a)). This Court also has jurisdiction pursuant to 28 U.S.C. § 1331 for an action arising under the federal Defend Trade Secrets Act of 2016 (18 U.S.C. § 1836 et seq.).

10. Venue is proper pursuant to 28 U.S.C. § 1391 because the parties are subject to personal jurisdiction in this district. The 2007 Agreement provides that "[a]ny action, suit or other proceeding pursuant to, arising under, or touching or concerning this Agreement or the transactions contemplated hereby shall be brought exclusively in any court of competent jurisdiction in New York, New York, United States of America" (Section 10.1(b)). Silimed and Sientra further agreed "to take any and all necessary or appropriate action to submit to the exclusive jurisdiction of any such court" (*id.*).

FACTS

A. Silimed's Valuable Breast Implant Business

11. Founded in 1978, Silimed offers the world's largest and most diverse line of medical-grade silicone products, with a catalogue of over 5000 items which are sold in more than 75 countries on five continents. Headquartered in Brazil, it is the largest manufacturer of silicone mammary implants in South America, has been Brazil's leading supplier of silicone implants for many years, and is the third largest manufacturer of such products in the world. The United States is one of Silimed's largest and most important markets for breast implants.

12. A breast implant is a prosthesis used to change the size, shape, and contour of a woman's breast. In reconstructive plastic surgery, breast implants are used to restore a natural-looking breast mound for post-mastectomy breast reconstruction patients or to correct congenital defects and deformities of the chest wall. They are also used cosmetically to enhance or enlarge the appearance of the breast through breast augmentation surgery. In the United States, breast implants are regulated by the FDA as medical devices. According to the FDA, approximately 5-

10 million women worldwide have breast implants, including as a result of breast reconstruction surgery.

13. Over a 35-year period, Silimed has invested substantial skill, labor, and capital into the development, manufacture, and marketing of its innovative line of products. Silimed's breast implants are silicone-based, meaning that they are pre-filled with silicone gel – a thick fluid that closely mimics the feel of human fat, and look and feel more like natural breast tissue. Many physicians consider silicone implants to be a superior alternative to the saline-filled implants offered by many of Silimed's competitors.

14. Silimed has continuously manufactured silicone breast implants since 1981. Silimed has developed new and innovative methods for the manufacture of mammary implants with different textures and, in 1996 and 1997, perfected a proprietary method of texturization (which it called TRUE Texture™). Use of Silimed's proprietary TRUE Texture™ method results in a unique structure of peaks and valleys that creates pores, reducing the incidence of capsular contracture. In March 2012, Silimed became the first manufacturer in the world to have anatomical silicone mammary implants approved by the FDA. The Silimed products approved by the FDA include both smooth and textured mammary implants.

15. Silimed's confidential and proprietary technology and manufacturing know-how includes, without limitation, the following: (a) specifications and manufacturing instructions related to shell configuration and structure, including documents specifying the form in which the layers are arranged and their thickness; (b) the overcoat processes and specific ammonium carbonate particle grain sizes and ratios used to obtain the roughness of the surface, peaks and valleys, and density of pores by the use of Silimed's TRUE Texture™ method and related manufacturing techniques; (c) the gel process used to arrive at the penetration and tactile

perceptions of the various Silimed products; (d) the mandrel sizes and CAD design for the various Silimed products; (e) the specifications of the support tool used to cure the filling gel, and the weight specifications of the shim; and (f) the tolerance range specifications of the dimension and weight specification of each product.

16. Taken together, this confidential and proprietary technology allows Silimed to manufacture products with unique attributes that give it an important advantage over competitive products with both patients and physicians. Sientra has acknowledged both the proprietary nature of Silimed's technology and the unique attributes of its products, as well as the competitive advantage they offer. For example, Sientra's website notes that TRUE Texture™ is "Silimed's proprietary texturing method designed to promote better tissue adherence" (available at http://sientra.com/breast-implants.php) (noting further that the Silimed implants are the only FDA-approved 5th generation round implants). The competitive advantages of the Silimed products distributed by Sientra in North America have been recognized not only by physicians and customers, but by investors and analysts as well.

B. The Relationship Between Silimed and Sientra

17. In 2007, Sientra (then known as Juliet Medical, Inc.) acquired Silimed's existing U.S. distributor, Silimed Inc., a Texas corporation ("Silimed Texas"). While Silimed Texas bore the Silimed name, it was not owned or controlled by Silimed and had no manufacturing capabilities or expertise. In connection with the acquisition, Silimed and Sientra entered into the 2007 Agreement, pursuant to which Silimed granted to Sientra the exclusive right to distribute certain Silimed products, principally Silimed's breast implants, in the United States and Canada.

18. As was the case with Silimed Texas, Sientra had no manufacturing capabilities and agreed to act as a distributor of Silimed's products. As of 2007, Silimed Texas had applied

for but not yet obtained FDA approval to sell Silimed breast implant products in the United States, based upon, among other things, clinical tests it had conducted using Silimed products.

19. Sientra paid Silimed Texas to secure the rights to its clinical testing data and PMA application which, once granted, would provide Sientra with access to the lucrative U.S. market. Sientra also assumed the exclusive license and distribution agreement between Silimed and Silimed Texas, which was renegotiated and restated in order to confirm the protection of Silimed "Manufacturer IP" and "Confidential Information" (which terms were expressly defined in the 2007 Agreement and are discussed further below). Sientra thereby obtained a license to market Silimed products in the United States and Canada for a period of 10 years. Under the 2007 Agreement (Sections 5.1 and 5.6), Sientra was responsible for obtaining and maintaining necessary regulatory approvals, including obtaining the PMA from the FDA.

20. Sientra understood that the Silimed license and PMA application were valuable because of the superiority of the Silimed products, and the fact that there were few competitors in the U.S. market due to the high barriers to entry, including regulatory restrictions.

21. An application to the FDA for a PMA must provide (among other things) a complete description of the device (including pictorial representations), and detailed information on each of the functional components or ingredients of the device, the properties of the device, the principles of operation of the device, and "the methods, facilities, and controls used in the manufacture, processing, packing, storage, and where appropriate, installation of the device in sufficient detail so that a person generally familiar with current good manufacturing practices can make a knowledgeable judgment about the quality control used in the manufacture of the device" (*see* PMA Application Contents, available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/P

remarketSubmissions/PremarketApprovalPMA/ucm050289.htm; *see also* 21 U.S.C. § 360e; 21 C.F.R. § 814). To the extent information to be submitted to the FDA constitutes a trade secret or includes other confidential commercial or financial information, such information can be designated as confidential and may not be disclosed by the FDA. *See* 21 C.F.R. § 20.61 and 21 C.F.R. § 814.9.

22. As provided by the 2007 Agreement (Section 5.1), Sientra requested and obtained from Silimed for submission to the FDA confidential and proprietary information (including trade secret information and know-how) related to the design, implementation, performance and manufacturing method of Silimed's breast implant products, including "Manufacturer IP," as that term is defined in the 2007 Agreement (Section 1.1). Silimed shared confidential and proprietary information with Sientra for the sole purpose of allowing Sientra to carry out its obligations under the 2007 Agreement, and based on Sientra's express undertaking that such information was, and would remain at all times, confidential and proprietary to Silimed.

23. Confidential and proprietary information provided by Silimed to Sientra for purposes of obtaining and maintaining the PMA took, without limitation, the following form: (a) device master records and product manufacturing specifications; (b) directions for use; (c) drawings, including of products, molds, templates, assembling, and semi-finished products; (d) reports of risk study management; (e) technical documentation and studies; (f) validation reports; (g) printing templates; (h) tables, including of shell dipping specifications, filling specifications, shell thickness, QC inspections specifications criteria, and manufacturing process parameters; (i) manufacturing, quality control and inspections instructions; (j) labeling specifications; and (k) design files, each relating to Silimed's breast implant products.

24. Silimed understood that all of the confidential and proprietary information it provided to Sientra for submission to the FDA was to be treated and marked as confidential, trade secret information by Sientra in its FDA submissions and that it would not be made available to the public or to Silimed's competitors under the relevant FDA rules.

25. Both parties understood that the manufacturing information provided by Silimed was unique, valuable, proprietary and competitively sensitive, and that its value was due in large part to its continued confidentiality.

26. The FDA granted Sientra a PMA for Silimed products in 2012. The PMA, as well as later supplements thereto, was limited to Silimed-manufactured products, made to Silimed specifications at Silimed's facilities in Brazil. Silimed's proprietary manufacturing information, including the precise specifications and procedures that it provided to Sientra, was and remains essential to obtaining and maintaining the PMA, and any supplements thereto.

27. Changes to Silimed's texturing method or other manufacturing procedures could affect, among other things, the collection of fluid around the implant (seroma rate) or have other health implications. Such changes could even affect the clinical results that serve as the basis for the PMA.

28. Under the relevant FDA rules, modifications to manufacturing procedures or methods of manufacture that affect the safety and effectiveness of a device subject to an approved PMA require submission of a supplement for review and approval by the FDA. Demonstration that the proposed modification is acceptable would require a significant investment of time and resources, and the risk would nonetheless remain that the FDA reject the modification and/or request additional testing or information. Faced with expiration of the 2007 Agreement in April 2017, Silimed was under pressure to develop a facility to manufacture breast

implant products that could be expected to commence production and receive FDA approval in the shortest possible time. It understood that it could best achieve this goal by misappropriating Silimed's proprietary manufacturing information. Without that information, Sientra would have had to spend substantial additional time and money developing a manufacturing facility without any assurance that it could have used a supplement to the existing PMA or developed a product in a short period of time that would be acceptable to its customers.

29. The mutual understanding concerning Silimed's confidential and proprietary information is reflected in the 2007 Agreement, the relevant provisions of which are described below.

C. The 2007 Agreement

30. Silimed and Sientra provided in the 2007 Agreement for the protection of Silimed's Confidential Information and Manufacturer IP, and provided that Sientra could use such information solely for purposes of performing the 2007 Agreement.

1. Manufacturer IP

31. Through its definition of "Manufacturer IP," the 2007 Agreement (Section 1.1) provides that Silimed owns: (a) all of the IP Rights that Silimed, as creator and manufacturer of its breast implant products, held prior to December 1, 1997 (when Silimed first entered into a U.S. distribution agreement with Silimed Texas); (b) IP Rights acquired by Silimed from another Person; and (c) IP Rights conceived, authored, created or otherwise developed by or on behalf of Silimed at any time; in each case to the extent that they relate to the Products or the Product Specifications (including processes and know-how for the manufacture thereof).

32. The 2007 Agreement broadly defines "IP Rights" to include not only "Confidential Information, including trade secrets and know-how," but also:

> all other intellectual property rights or industrial property rights of any kind or nature (whether or not protectable under patent, copyright, trade secrecy or similar laws) that are conceived, discovered, developed, created or reduced to practice or tangible medium of expression by consultants or employees of a party to this Agreement (or by Silimed, Inc. in the case of Juliet Medical, Inc. as a party) without the use of IP Rights owned or Controlled by the other party to this Agreement (or by Silimed Inc. in the case of Juliet Medical, Inc. as a party) or are otherwise Controlled by such party (or by Silimed Inc. in the case of Juliet Medical, Inc. as a party).

(Section 1.1) (emphasis added).

33. "Products" is defined in the 2007 Agreement as "all products for all medical applications which are now or which may hereinafter become a part of the Manufacturer's [*i.e.,* Silimed's] line of products" (*see id.*) (emphasis added).

34. The 2007 Agreement specifically and effectively limits Sientra's "Company" IP Rights to those owned by Silimed Texas, the former U.S. distributor, prior to December 1, 1997. This by definition does not include the extensive Silimed confidential and proprietary "Manufacturer IP" developed prior to 1997, between 1997 and 2007, and after 2007. Although the 2007 Agreement also includes as "Company IP" any IP Rights relating to the Products that Sientra acquired from another Person during the term of the 2007 Agreement, or that were "conceived, authored, created or otherwise developed by or on behalf of Sientra after December 1, 1997," no Manufacturer IP was acquired by Sientra in this manner.

35. The 2007 Agreement, which was entered into contemporaneously with Sientra's purchase of the assets of Silimed Texas, further confirms that no Manufacturer IP is or has been conveyed to Sientra, expressly stating that "this [2007] Agreement does not convey to [Sientra] any right, title or interest in or to any Manufacturer IP by implication, estoppel or otherwise except for the license rights expressly granted under Section 4.2" (Section 4.4) (emphasis added).

Section 4.4 of the 2007 Agreement further provides that "Title to the Manufacturer IP shall at all times remain vested in Manufacturer."

2. Confidential Information

36. Under the 2007 Agreement, "all data, specifications, training and any other trade secrets or know-how related to the design, implementation, performance or manufacture of the Products" are to be treated as Confidential Information. Confidential Information also includes "all other information and data provided by either party to the other party pursuant to this Agreement [...] and marked as confidential," subject to certain limitations (Section 1.1) (emphasis added).

37. Silimed and Sientra exchanged confidential information with this understanding.

3. Confidential Information and Manufacturer IP Was Provided to Sientra Under a Limited License and for a Limited Purpose

38. Silimed provided Sientra with Manufacturer IP and Confidential Information for the limited purpose of allowing Sientra to perform its obligations under the 2007 Agreement, which was limited to a 10-year term.

39. Specifically, Silimed only granted Sientra the right (a) to use Silimed's trademarks in the United States "in connection with the promotion, marketing, advertising, and sale of Products in the Territory;" and (b) to use "other Manufacturer IP" "as necessary or useful to promote, sell and deliver the Products in the Territory" (Section 4.2(a)) (emphasis added).

40. Similarly, Silimed agreed to provide Sientra with product samples, upon request, only for testing, regulatory approvals, and demonstration and marketing purposes (Section 3.9). Likewise, Sientra was granted access to Silimed information and facilities in connection with Sientra's inspections only "to the extent necessary, and for the sole purpose" of assessing

Silimed's compliance with the quality control and product warranty obligations under the agreement (Section 5.3).

4. The Confidentiality Agreement

41. The provision of Silimed's manufacturing information was at all times subject to the confidentiality obligations set forth in the 2007 Agreement, which prohibit the unauthorized use or disclosure to third parties of Confidential Information.

42. Specifically, the confidentiality obligations provide that "Company shall not use for any purpose other than this Agreement and shall not reveal or disclose to third parties the subject matter of this Agreement and any Confidential Information received from the other party as confidential in nature." (Section 4.1(a)) (emphasis added).

43. Section 4.1 further provides:

> Any Confidential Information disclosed by either party hereunder to the other party may be used only by employees of the other party or its affiliates who agree to be bound by such party's obligations hereunder with respect to such Confidential Information and who have a genuine need to know such information for the purposes permitted by this Agreement.

44. The confidentiality obligations of the 2007 Agreement survive termination or expiration of the 2007 Agreement (Section 8.3), which was limited to a 10-year term. At such time, Sientra is required to "discontinue any and all use of the licenses granted under Section 4.2" (*id.*). Upon termination or expiration, Sientra must return or certify that it has destroyed "all documents and other tangible items it or its employees have received or created pertaining, referring or relating to the Confidential Information of [Silimed]" (*id.*).

D. Other Steps Taken to Protect Silimed's Confidential Information

45. Silimed has taken reasonable measures to maintain and protect its trade secrets and confidential information. In addition to the above contractual protections, Silimed

employees and consultants were informed of and understood the confidential nature of Silimed's manufacturing IP, and access to such information was restricted to those employees on a need-to-know basis. Beginning no later than 1996, Silimed implemented a policy and employee training for the elaboration, approval, alteration and controlled distribution of technical documents. All employees with access to such information received training on this procedure.

46. Beginning no later than 2010, Silimed has required employees to agree to and sign the company's policy on the use of IT resources, which codified and improved the company's existing practice. Among other things, Silimed mandated password-protected user authentication to validate and authorize access to its IT resources, with obligatory alteration of access passwords taking place every 90 days. Internet access was filed for auditing (including as to the access date, the user who performed the access, and protocols used), and access through means other than the Silimed networks was strictly forbidden. In addition, Silimed mandated that users of its IT resources only use the company server to store their working documents. The use of portable storage devices required authorization and encryption, and their use was restricted to the Silimed facilities. Silimed expressly reserved the right to bring a legal action for non-compliance with its policy "in order to repair damages to its image, credibility, facilities, properties, secrecy or harms caused to its business," as well as other cases authorized by law.

47. The success of these efforts is demonstrated by the fact that Silimed manufacturing information has not become available to competitors and its products continue to enjoy a competitive advantage in the marketplace.

E. Breach of the Confidentiality Agreement and Wrongful Conduct by Sientra

48. Sientra willfully and repeatedly breached numerous provisions of the 2007 Agreement, violated New York and federal laws prohibiting misappropriation of trade secrets,

violated its duty of good faith and fair dealing, and engaged in unfair competition by using Silimed's Confidential Information and Manufacturer IP to develop its own manufacturing capability, which it intends to use to manufacture Silimed products without any license and in competition with Silimed.

1. Sientra's Unsuccessful Efforts to Purchase Silimed and Its Scheme to Expropriate Silimed IP to Set Up A Competing Manufacturing Facility

49. Beginning as early as 2005, Sientra's then-CEO, Hani Zeini, repeatedly expressed an interest in purchasing Silimed Brazil. Sientra viewed the Silimed Texas acquisition as an initial step to achieving this goal. Following the assumption of Silimed Texas's distribution rights (in exchange for the obligation to obtain and maintain regulatory approvals), Sientra continued to pursue its acquisition objectives and made numerous overtures in this regard. However, Silimed refused to sell.

50. On information and belief, as early as 2015, faced with Silimed's refusal to allow itself to be purchased by Sientra, and with the 2007 Agreement set to expire in April 2017, Sientra embarked upon a scheme to misappropriate Silimed's Manufacturer IP and Confidential Information. It did so in order to be in a position to operate a competing facility capable of manufacturing Silimed products following the termination or expiration of the 2007 Agreement. Because the PMA is limited to Silimed-manufactured products, produced to Silimed specifications, it will be essential for Sientra to obtain and use proprietary Silimed manufacturing know-how and other confidential information if it wants to sell under the present PMA or obtain a supplement thereto. It would take Sientra years to develop and obtain FDA approval for a new design.

51. As early as August 2015, Sientra secretly established a partnership with Vesta, a contract manufacturer of silicone products and other medical devices owned by the Lubrizol

Corporation. The objective of the collaboration was specifically to develop the capacity to manufacture Silimed-designed breast implant products. This arrangement was not disclosed to Silimed until August 2016.

52. On information and belief, commencing in 2015, if not earlier, Sientra has taken improper advantage of its contractual relationship with Silimed to misappropriate valuable Silimed Manufacturer IP, Confidential Information, and other proprietary information and know-how. Under the 2007 Agreement, Sientra had access to and was able to use Silimed Manufacturer IP and Confidential Information solely for purposes of performing the 2007 Agreement, and principally to obtain and maintain the PMA. Sientra repeatedly requested and was provided with Manufacturer IP and Confidential Information ostensibly for use in FDA applications. Sientra also obtained extensive additional Silimed proprietary information through site visits, audits and requests for supplemental information, again ostensibly for the purpose obtaining, maintaining and supplementing the PMA.

53. For example, on several occasions, including between June and November 2015, Sientra's VP of Product Development, Dan Carlisle, requested and received from Silimed confidential and proprietary information that, in hindsight, was requested for use – or on information and belief has otherwise been used – by Sientra in developing a competing manufacturing facility. At the time, Silimed reasonably believed that Sientra was requesting such information for purposes of performing the 2007 Agreement, notably for distribution of Silimed's products in the North American market, and would not have otherwise provided this information.

54. Similarly, when Silimed permitted Sientra site visits, or responded to requests for proprietary manufacturing information, it did not know that Sientra was developing its own

manufacturing capability and was going to use the requested information for that purpose. On the contrary, at the time, Silimed understood that these visits and requests were being made in connection with the regulatory approvals sought for purposes of performing the 2007 Agreement, and that the confidentiality of its manufacturing information and other know-how would be protected. Silimed would not have provided Sientra with access to its manufacturing facility or provided manufacturing information if it had known that Sientra intended to use such information to establish a competing facility to manufacture unlicensed Silimed products.

55. On information and belief, Sientra has used and/or disclosed Silimed Manufacturer IP and Confidential Information in breach of the 2007 Agreement and in violation of Silimed's rights, including to further Sientra's project with Vesta. Without limiting the generality of the foregoing, on information and belief, Sientra has used and/or disclosed some or all of the following information provided by Silimed:

(a) specifications and manufacturing instructions related to shell configuration and structure, including documents specifying the form in which the layers are arranged and their thickness;

(b) the overcoat processes and specific ammonium carbonate particle grain sizes and ratios used to obtain the roughness of the surface, peaks and valleys, and density of pores by the use of Silimed's TRUE Texture™ method and related manufacturing techniques;

(c) the gel process used to arrive at the penetration and tactile perceptions of the various Silimed products;

(d) the specifications of the support tool used to cure the filling gel, and the weight specifications of the shim; and

(e) the tolerance range specifications of the dimension and weight specification of each product.

2. September 2015 Regulatory Suspensions

56. In September 2015, an inspection of Silimed's Brazilian manufacturing facility found the presence of silicone particles on Silimed breast implants, prompting certain regulatory inquiries. On September 23, 2015, the UK Medicines and Healthcare Products Regulatory Agency ("MHRA") announced the suspension of sales and implanting in the United Kingdom of Silimed breast implants, although MHRA also noted that no risk to patients' health had been identified. Silimed's ANVISA Brazilian manufacturing authorization was temporarily suspended from September 25, 2015 to January 27, 2016. In an unrelated event, on October 22, 2015, a fire took place at the "F2" building at Silimed's Brazilian manufacturing facility, causing Silimed to transfer manufacturing to its "F1" building.

57. Although the FDA was informed of these developments and had taken no measure against Silimed's breast implant products, on October 9, 2015, Sientra voluntarily (and temporarily) placed a hold on the sale of Silimed products in the United States. During that time period, Sientra provided the FDA with information demonstrating that the presence of the silicone particles did not entail any health risk. On February 8, 2016, Sientra announced the return of all Silimed products to the U.S. market as of March 1, 2016. In announcing the market return, Sientra confirmed that the conclusive results of its independent testing gave it confidence in the safety of Silimed breast implant devices.

58. Although Sientra independently validated and publicly affirmed the safety of Silimed's breast implant devices, on information and belief, Sientra saw Silimed's regulatory issues and fire as an opportunity to attempt to extort from Silimed a royalty-free license for its confidential and proprietary technology. Sientra thereupon set upon a course of conduct

designed to cause Silimed further economic duress, and to weaken its business, in the hope that Silimed would be unable to resist Sientra's unjustified demands.

59. First, Sientra refused to pay outstanding invoices in the amount of $2,135,140 plus interest. This refusal was despite the fact that the 2007 Agreement provided that, even in the event of a dispute, both parties would "continue their performance under this Agreement including, without limitation, the payment of all amounts due to the other party" (Section 9.2). Sientra only agreed to pay the outstanding invoices and purchase certain inventory on or about August 5, 2016, after Silimed provided a notice of termination of the 2007 Agreement for Sientra's material breach thereof, which was only withdrawn upon payment.

60. Second, Sientra refused to share with Silimed information that Sientra had accumulated affirming the continued safety of Silimed products. In response to the regulatory suspensions described above, Sientra announced that it had obtained the results of third-party testing demonstrating the safety of Silimed's breast implant products. This included information that Sientra has submitted to the FDA, which would have assisted Silimed in resolving the above-referenced regulatory issues in other jurisdictions. Silimed repeatedly requested copies of such studies. For example, on or about January 11, 2016, Silimed's CEO requested information from Sientra's CEO that could be used in scheduled regulatory meetings in Europe. Yet this and other Silimed requests were refused.

61. Sientra's refusal was in violation of its obligation under the 2007 Agreement to "cooperate with all of Manufacturer's efforts to obtain and maintain regulatory approvals for the manufacture of the Product at the Facility, including, without limitation, by providing Manufacturer and the Regulatory Authority with such information and assistance as Manufacturer may reasonably request regarding the Product" (Section 5.1(b)). The refusal was

also in violation of Sientra's obligation to "promptly provide reasonable advice and assistance [...] as may be necessary to obtain and maintain approvals for the Facility, Applicable GMPs for the manufacture of the Products and Product Approvals for the Products" (Section 5.1(c)).

62. Third, the transfer by Silimed of its manufacturing from its "F2" building to its "F1" building required a supplement to the PMA. However, Sientra refused to assist with the required FDA submission and inspections, in violation of its "sole responsibility and authority" to obtain and maintain FDA approvals, and its obligation to use "commercially reasonable efforts" to do so (Section 5.1). Silimed first informed Sientra that it was willing and able to transfer manufacturing to F1 on or before October 28, 2015. In addition, Silimed presented Sientra with proposals to transfer manufacturing to F1 on several occasions, including at a meeting of the companies' CEOs in Brazil on or about December 15, 2015, and again on or about March 28, 2016. However, Silimed's manufacturing proposals remain unanswered.

63. Following these efforts to harm Silimed's business, on March 11, 2016, Sientra caused its counsel, Cooley LLP, to demand on its behalf that Silimed turn over "on a perpetual, royalty-free basis…all technology and proprietary or intellectual property rights necessary to enable Sientra or its designee to manufacture such products, and provide Sientra or its designee with assistance, at Sientra's expense, in establishing a manufacturing line." It demanded further that Silimed "agree not to sell or provide products either directly or to any third party for use or to be used in the United States."

64. This demand was accompanied by an entirely unjustified and unsubstantiated claim for alleged indirect and consequential damages expressly barred by the 2007 Agreement. Sientra had been sued on or about September 25, 2015 by a class of shareholders alleging that Sientra has failed to make adequate disclosures under U.S. federal securities regulations. In the

Cooley LLP letter, Sientra further sought to hold Silimed responsible for the inadequacies of Sientra's SEC disclosures concerning the regulatory issues involving Silimed, which had resulted in securities law claims being filed against Sientra. In fact, Sientra had been kept fully informed of Silimed's regulatory issues, and any deficiencies in Sientra's SEC disclosures were solely its own responsibility.

65. When Silimed rejected Sientra's demand for a free license, Sientra undertook to negotiate a license, for a substantial fee, to use Silimed's Confidential Information and Manufacturer IP to manufacture Silimed products for sale in the U.S. and Canadian markets. For over four months, Silimed's CEO, Gabriel Robert, negotiated with Sientra's CEO, Jeff Nugent. However, these negotiations have failed to result in a license.

3. Silimed's Continued Efforts to Protect its Rights

66. Silimed has been vigorous in enforcing the contractual obligations binding Sientra. For example, when confronted with suspicions about Sientra's compliance with the 2007 Agreement, Silimed immediately sought confirmation from Sientra that it was not using or disclosing Silimed's Manufacturer IP or Confidential Information for purposes outside the scope of what is permitted under the 2007 Agreement.

67. Sientra failed to provide an accurate and complete response to Silimed's notices and requests for assurances. At the same time, Sientra has not denied that it is using or disclosing information obtained from Silimed through site visits, audits and requests for information under the 2007 Agreement to develop an unlicensed and competing manufacturing facility. Nor has Sientra replied to requests designed to determine whether it has put in place a "clean room" for its product development activities. This failure suggests that Sientra has not done so.

68. More recently, Sientra has begun to assert that it owns the Silimed Manufacturer IP and Confidential Information necessary to enable it to manufacture Silimed breast implant products under a supplement to the existing PMA. These recent assertions are entirely at odds with both the provisions of the 2007 Agreement and with Sientra's past conduct and statements, most notably the repeated offers of its former CEO, Mr. Zeini, to purchase Silimed and its Brazilian manufacturing operations, as well as its efforts to negotiate a manufacturing license.

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COUNT I – BREACH OF CONTRACT

69. Plaintiff repeats and realleges all of the allegations set forth in paragraphs 1 through 68 as if fully set forth herein.

70. The 2007 Agreement is a valid, binding, and enforceable agreement.

71. Under the 2007 Agreement, Sientra recognized the limited scope of its license to distribute Silimed's breast implant products in the U.S. and Canadian markets, and in particular that Sientra could only use proprietary manufacturing information provided by Silimed for purposes of performing the 2007 Agreement.

72. Specifically, Silimed only granted Sientra the right (a) to use Silimed's trademarks in the United States "in connection with the promotion, marketing, advertising, and sale of Products in the Territory;" and (b) to use "other Manufacturer IP" "as necessary or useful to promote, sell and deliver the Products in the Territory" (Section 4.2(a)) (emphasis added).

73. Sientra further agreed to "not use for any purpose other than this [2007] Agreement," and to "not reveal or disclose to third parties" Confidential Information received from Silimed, including data, specifications, training and any other trade secrets or know-how related to the design, implementation, performance or manufacture of the Products (Section 4.1).

In addition, Sientra agreed that employees to whom such Confidential Information was provided would be bound by the terms of the confidentiality obligations contained in the 2007 Agreement. Sientra also agreed to take reasonable measures to ensure that no unauthorized use or disclosure of Confidential Information takes place.

74. Sientra has breached its obligations to Silimed under the 2007 Agreement, including without limitation by failing to use Silimed's Confidential Information and Manufacturer IP solely as authorized under the 2007 Agreement. Among other things, on information and belief, Sientra has unlawfully used and/or disclosed Silimed's proprietary manufacturing information in connection with its efforts to establish a competing manufacturing facility to replicate the Silimed line of products, including disclosure of such information to Vesta and other undisclosed third parties to further this purpose. In addition, on information and belief, Sientra has unlawfully used and/or disclosed or intends to use and/or disclose such confidential and proprietary information in requesting or seeking to request a supplement to the existing PMA that specifically covers Silimed-manufactured products, made to Silimed specifications, at Silimed's facilities in Brazil. Sientra intends to use such a PMA supplement to permit itself or a third party to establish a competing manufacturing facility to replicate the Silimed line of products, in violation of the 2007 Agreement.

75. In addition, on information and belief, Sientra further breached the 2007 Agreement by improperly revealing or disclosing Silimed's confidential and proprietary manufacturing information to Vesta and other undisclosed third parties in connection with its announced manufacturing plans.

76. In engaging in the conduct described above, Sientra has also breached the implied covenant of good faith and fair dealing.

77. Sientra's multiple breaches of the 2007 Agreement have caused, and continues to cause, damage to Silimed. Indeed, Sientra understood that the confidential manufacturing information provided by Silimed was unique, valuable, proprietary and competitively sensitive, and that its value was due in large part to its continued confidentiality.

78. Silimed is entitled to compensatory damages for Sientra's use of Silimed's Manufacturer IP and Confidential Information to gain an advantage in the context of establishing its own manufacturing capability, in an amount to be determined at trial.

79. Money damages alone are not sufficient to remedy the harm caused to Silimed by Sientra's use and public disclosure of its Manufacturer IP and Confidential Information. Rather, Silimed has suffered and will continue to suffer irreparable harm as a result of Sientra's use and public disclosures including, without limitation, permanent ongoing harm to Silimed, who derives economic value from its Manufacturer IP and Confidential Information not being generally known to or readily ascertainable by third parties who can obtain economic benefit from its use.

80. In light of the above considerations, and pursuant to the terms of the 2007 Agreement, Silimed requests an injunction in the form articulated in the prayer below.

COUNT II – UNFAIR COMPETITION

81. Plaintiff repeats and realleges all of the allegations set forth in paragraphs 1 through 68 as if fully set forth herein.

82. Silimed has invested substantial skill, labor, and capital for over 35 years into the development, manufacture, and marketing of its innovative line of products. Silimed's confidential and proprietary manufacturing information (including trade secrets and know-how)

allows it to manufacture products with unique attributes that give it an important competitive advantage in the marketplace.

83. Sientra was provided with Silimed's confidential and proprietary manufacturing information for the sole purpose of performing the 2007 Agreement, principally for obtaining and maintaining regulatory approvals for distribution of Silimed's products in the North American market. When Silimed shared such confidential and proprietary information with Sientra, it reasonably understood that Sientra would only use it for purposes of performing the 2007 Agreement, and that such information was, and would remain at all times, confidential and proprietary to Silimed. In violation of its obligation to use such information only for purposes of performing the 2007 Agreement, on information and belief, Sientra has used and/or disclosed Silimed's proprietary manufacturing information in connection with its efforts to establish a competing manufacturing facility to replicate the Silimed line of products, including disclosure of such information to Vesta and other undisclosed third parties to further this purpose. In addition, on information and belief, Sientra has used and/or disclosed, or seeks to use and/or disclose, Silimed's proprietary manufacturing information to request a supplement to the existing PMA for Silimed-manufactured products, made to Silimed specifications, at Silimed's facility in Brazil. Sientra's unfair competition is at the expense of Silimed, whose access to the North American market is restricted by virtue of the regulatory approvals process, including the need for a PMA.

84. Sientra knew that the manufacturing information provided by Silimed was and would remain at all times confidential and proprietary to Silimed. However, on information and belief, Sientra seeks to compete against Silimed worldwide using Silimed's confidential and proprietary manufacturing information.

85. Sientra's bad faith actions have caused and will continue to cause harm to Silimed, which derives economic value from its Manufacturer IP and Confidential Information not being generally known to or readily ascertainable by third parties who can obtain economic benefit from its use.

86. Silimed is thus entitled to preliminary and permanent injunctive relief to prevent Sientra from using and/or disclosing the confidential information it misappropriated from Silimed.

87. In addition, by virtue of Sientra's unfair competition, Silimed is entitled to compensatory and punitive damages in an amount to be determined at trial.

COUNT III – MISAPPROPRIATION OF TRADE SECRETS (NEW YORK)

88. Plaintiff repeats and realleges all of the allegations set forth in paragraphs 1 through 68 as if fully set forth herein.

89. Silimed's Manufacturer IP and Confidential Information, including, without limitation, trade secrets and know-how related to the design, implementation, performance and manufacturing method of Silimed's breast implant products, was and is valuable trade secret information, requiring specialized knowledge and information that is vital to Silimed's business operations, which Silimed uses worldwide. Sientra understood that the manufacturing information provided by Silimed under the 2007 Agreement was unique, valuable, proprietary and competitively sensitive, and that its value was due in large part to its continued confidentiality.

90. The confidential and proprietary manufacturing information provided by Silimed to Sientra is expressly protected by the terms of the 2007 Agreement, which was renegotiated and restated in order to confirm the protection of Silimed "Manufacturer IP" and "Confidential

Information." The 2007 Agreement further strictly limited Sientra's use of Silimed's confidential and proprietary manufacturing information, and prohibited any use not authorized under the 2007 Agreement.

91. Silimed has taken reasonable measures to maintain and protect its trade secrets and know-how. Silimed understood that all of the confidential and proprietary information that Silimed provided to Sientra for submission to the FDA was to be treated and marked as confidential, trade secret information by Sientra under the relevant FDA rules, and would not be made available to the public or to Silimed's competitors. Silimed's Manufacturer IP and Confidential Information was restricted to employees with a need to know such information, and who were educated about the confidential nature of the information. It is not generally known by and has not been made available to the public.

92. Silimed derives economic value from its Manufacturer IP and Confidential Information not being generally known to or readily ascertainable by third parties who can obtain economic benefit from its use. The success of efforts to maintain confidentiality is demonstrated by the fact that Silimed manufacturing information has not become available to competitors and its products continue to enjoy a competitive advantage in the marketplace.

93. Notwithstanding the measures taken to protect Silimed's trade secrets, Sientra misappropriated, and is exploiting for its own economic advantage, the Silimed Manufacturer IP and Confidential Information. In violation of its obligation to keep Silimed's proprietary manufacturing information confidential, on information and belief, Sientra has unlawfully used and/or disclosed Silimed's proprietary manufacturing information in connection with its efforts to establish a competing manufacturing facility to replicate the Silimed line of products, including disclosure of such information to Vesta and other undisclosed third parties to further

this purpose. In addition, on information and belief, Sientra has unlawfully used and/or disclosed or intends to use and/or disclose such confidential and proprietary information in requesting or seeking to request a supplement to the existing PMA that specifically covers Silimed-manufactured products, made to Silimed specifications, at Silimed's facilities in Brazil.

94. Without the Silimed manufacturing procedures and specifications – which served as the basis for the PMA – it would take Sientra years to develop and obtain FDA approval for a new product design.

95. Silimed is thus entitled to preliminary and permanent injunctive relief to prevent Sientra from using and/or publishing the confidential information it misappropriated from Silimed.

96. In addition, by virtue of Sientra's unfair competition, Silimed is entitled to compensatory and punitive damages in an amount to be determined at trial.

COUNT IV – MISAPPROPRIATION OF TRADE SECRETS (18 U.S.C. § 1836)

97. Plaintiff repeats and realleges all of the allegations set forth in paragraphs 1 through 68 as if fully set forth herein.

98. Silimed's Manufacturer IP and Confidential Information, including, without limitation, information related to the design, implementation, performance and manufacturing method of Silimed's breast implant products, was and is valuable trade secret information, requiring specialized knowledge and information that is vital to Silimed's business operations, which Silimed uses in both interstate and foreign commerce. Sientra understood that the manufacturing information provided by Silimed under the 2007 Agreement was unique, valuable, proprietary and competitively sensitive, and that its value was due in large part to its continued confidentiality.

99. Silimed shared confidential and proprietary information with Sientra for the sole purpose of allowing Sientra to carry out its obligations under the 2007 Agreement, and with Sientra's express understanding that such information was, and would remain at all times, confidential and proprietary to Silimed. Indeed, such information is expressly protected by the terms of the 2007 Agreement, which confirmed protection of Silimed's "Manufacturer IP" and "Confidential Information," strictly limited Sientra's use thereof, and prohibited any use not authorized under the 2007 Agreement.

100. Silimed has taken reasonable measures to maintain and protect its trade secrets and know-how. Silimed understood that all of the confidential and proprietary information that Silimed provided to Sientra for submission to the FDA was to be treated and marked as confidential, trade secret information by Sientra under the relevant FDA rules, and would not be made available to the public or to Silimed's competitors. Silimed's Manufacturer IP and Confidential Information were restricted to employees with a need to know such information, and who were educated about the confidential nature of the information. It is not generally known by and has not been made available to the public.

101. Silimed derives economic value from its Manufacturer IP and Confidential Information not being generally known to or readily ascertainable by third parties who can obtain economic benefit from its use. Silimed manufacturing information has not become available to competitors and its products continue to enjoy a competitive advantage in the marketplace.

102. Notwithstanding the measures taken to protect Silimed's trade secrets, Sientra misappropriated, and is exploiting for its own economic advantage, the Silimed Manufacturer IP and Confidential Information. In violation of its obligation to keep Silimed's manufacturing information confidential, on information and belief, Sientra has unlawfully used and/or disclosed

Silimed's proprietary manufacturing information in connection with its efforts to establish a competing manufacturing facility to replicate the Silimed line of products, including disclosure of such information to Vesta and other undisclosed third parties to further this purpose. In addition, on information and belief, Sientra has unlawfully used and/or disclosed or intends to use and/or disclose such confidential and proprietary information in requesting or seeking to request a supplement to the existing PMA that specifically covers Silimed-manufactured products, made to Silimed specifications, at Silimed's facilities in Brazil.

103. Without the Silimed manufacturing procedures and specifications – which served as the basis for the PMA – it would take Sientra years to develop and obtain FDA approval for a new product design.

104. Silimed is thus entitled to preliminary and permanent injunctive relief to prevent Sientra from using and/or publishing the confidential information it misappropriated from Silimed.

105. In addition, by virtue of Sientra's unfair competition, Silimed is entitled to compensatory and punitive damages in an amount to be determined at trial.

PRAYER FOR RELIEF

WHEREFORE, Silimed respectfully requests that, upon a final determination by this Court, judgment be entered in its favor and against Sientra as follows:

(a) On all Counts of the Complaint, a declaration that Sientra is in material breach of the 2007 Agreement for its improper use and disclosure of Silimed's Manufacturer IP and Confidential Information.

(b) On all Counts of the Complaint, a preliminary and permanent injunction ordering that:

(i) Sientra shall return or destroy all of Silimed's Confidential Information;

(ii) Sientra shall obtain the return of all disclosures of Silimed's Manufacturer IP and Confidential Information made to any third party, including without limitation any and all Manufacturer IP and Confidential Information provided to Vesta;

(iii) Sientra, and all third parties acting in participation or concert with Sientra or pursuant to license, permission, or authorization from Sientra, including without limitation Vesta, shall refrain from any further use or disclosure of Silimed's Manufacturer IP and Confidential Information, except for the limited purposes authorized under the 2007 Agreement until such time as the 2007 Agreement is terminated or expires, at which point Sientra shall return to Silimed or destroy all of Silimed's Manufacturer IP and Confidential Information;

(iv) Sientra shall provide a copy of the injunction order to each of its agents, employees, directors, officers, members, managers, parents, subsidiaries, or other entities or individuals acting or purporting to act on Sientra's behalf, or in participation or concert with Sientra or pursuant to license, permission, or authorization from Sientra ("Enjoined Parties"), who have received Silimed's Manufacturer IP and Confidential Information; and

(v) Sientra shall provide to Silimed and the Court a signed declaration under penalty of perjury from each of the Enjoined Parties who received the Court's injunction order, confirming that they have received and will comply with the injunction order.

(c) On all Counts of the Complaint, money damages, according to proof.

(d) On Counts II, III, and IV of the Complaint, punitive damages.

(e) Granting Silimed such other and further relief as the Court deems just and appropriate.

Dated: New York, New York
November 1, 2016

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